**Pending cases of export permission**

869. DR. V. MAITREYAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that many cases for registration/ NOC to manufacture/NOC to export and permission to manufacture new drugs are pending in the office of the Drug Controller General of India for more than two to three years;

(b) if so, the reasons for such delay to process the applications and the details of such pending cases under each category for the last three years, year-wise;

(c) whether it is also a fact that only selective cases are taken up for consideration and leaving a huge backlog for approvals in the department;

(d) the steps being taken to clear the pendancy and when it is likely to be cleared; and

(e) whether the Government proposes to introduce computerization of the licensing system in the commerce department to bring transparency and better efficiency in the functioning and if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (e) No, Sir, during last three years, the Office of the Drug Controller General of India received about 6000 applications for export, for which NOCs have already been issued. Besides export applications, about 5500 applications of various categories of new drugs which include investigational new drugs, new drug molecules, vaccines, biotech products, new fixed dose combinations, subsequent approvals, new dosage forms, new indications etc. were also received during the said period. Details of the drugs including fixed dose combinations, approved for the first time, during the last three years are available at website **www.cdsco.nic.in.** During the said period about 2000 subsequent approvals of new drugs, already approved in the country, have also been issued. Rest of the applications are under various stages of evaluation viz. clinical trial, bioequivalence study, laboratory testing, seeking further information from the applicants etc.

The evaluation of new drug applications wherein establishing safety and efficacy of the drug in humans is of paramount importance, is a complex process as per Schedule-Y under Drugs & Cosmetics Rules and varies according to the nature of molecule/drug, published data and information furnished by the applicants. It involves examination of chemical & pharmaceceutical informations, animal pharmacological & toxicoligical data, clinical data of safety & efficacy, laboratory testing etc. Depending upon the nature of the application, it may take on an average 3 to 5 years for an applicant to complete all phases of trials required for approval of investigational New Drug (i.e. a drug molecule not tested on human being anywhere in the world); about 1-3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial, and about 2-3 months for subsequent applications for already approved drugs. This is however, subject to submission of all required data as per provisions of Schedule-Y of Drugs & Cosmetics Rules.

Government is planning to introduce computerization, to bring transparency and better efficiency in the functioning, when the proposed Central Drugs Authority (CDA) is in place. The Drugs and Cosmetics (Amendment) Bill, 2007 in this regard has already been introduced in the Parliament.